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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/908,852	08/08/97	ROE	D 5494CR

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EXAMINER	
POLUTTA,M	
ART UNIT	PAPER NUMBER
3761	9

DATE MAILED: 05/12/99

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary	Application No. 08/906,852	Applicant(s) Roe
	Examiner M. Polutta	Group Art Unit 3761

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 3/2/99.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-27 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-27 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 112

1. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 27, it is unclear if applicant is claiming the wearer, the article or the method of use. Applicant claims the "lotion is transferred to the skin of a wearer", thus he positively recites the human body, which is non-statutory subject matter. From applicant's comments, it appears that applicant is not claiming a human body.

Claim Rejections - 35 U.S.C. § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreier et al. (5,171,236) in view of Buchalter (3,896,807) further in view of Duncan (3,489,148).

Dreier discloses a disposable diaper including a topsheet, a backsheet and an absorbent core wherein the topsheet is made from a hydrophilic material. (7:60-8:10)

Buchalter discloses an oil phase empregnant in the form of a non-oily solid that forms a cream upon the application of perspiration and heat (3:10-12) that is used on articles such as facial mask, slippers, sanitary napkins, diapers and diaper liners wherein the therapeutic cream is applied to the skin. (3:14-20) The wear's skin will produce sufficient moisture and heat to cause emulsification of a portion of the oil phase. The substance is dry non-oil non-greasy solid at room temperature (6:13-16) and it is essentially free from water. (6:51-53)

The formulation is made from about 1% to about 99% and preferably from about 30% to about 70% of an oily material which includes mineral oil and petrolatum (3:30-40), and from about 99% to about 1% and preferably from about 30% to about 70% of an immobilizing agent. The resulting preparation can be applied to the article in a liquid phase and cooled to form a solid oil phase (6:38-40).

The oil phase may additionally include, but are not limited to paraffin, vegetable oils, animals oils and isopropyl palmitate (3:35-41). The oil phase is in the form of a dry, nonoily, nonsticky solid at room temperature, and comprises an oily material and one or more emulsifying agents and may include in addition, one or more emollients etc. (2:32-50) It is important that water is not present in the oil phase before emulsification (6:51-53).

The immobilizing agent or emulsifying agent includes cetyl alcohol, long chain fatty acid partial esters of a hexitol anhydride wherein the fatty acid has at least 6,

preferably from 12 to 18, carbon atoms including the long chain fatty acid partial esters of sorbitan, sorbide, mannitan and mannide and mixtures thereof (3:42-55), polyoxylalkyne derivatives and soaps of aliphatic acids (4:9-50) The emusifing agent appears to be an equivalent to applicants' immobilizing agent.

Duncan discloses a diaper including a topsheet with a discontinuous coating of oleaginous substance beneficial to the skin in a localized area of the topsheet.

Dreier discloses an absorbent product including a hydrophilic topsheet. Buchalter teaches that it is known to apply a skin care product to sanitary napkins and diapers that will emulsify a portion of the oil phase upon moisture and heat and Duncan teaches applying a lotion nonuniformly to a central portion of a topsheet. It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a lotion as taught by Buchalter to prevent chafing or chapping of the skin, to a diaper as taught by Dreier in a nonuniform manner since Buchalter's substance is not greasy and oily and Duncan further teaches that a continuous coating is not needed, as it will avoid a greasy look and feel and will additionally save money.

It would have been obvious to one having ordinary skill in the art at the time the invention was made as a matter of design choice to apply the lotion in stripes wherein the immobilizing agent comprises a polyhydroxy fatty acid ester or a polyhydroxy fatty acid amide having the specific formulas as in claims 24 or 25 or an agent such as paraffin wax, since applicant has not disclosed that the particulars unexpectedly solves

any stated problem or is for any particular purpose and it appears that the invention would perform equally well as disclosed by Buchalter and Duncan and Dreier.

I must conclude that the use apply the lotion in stripes wherein the immobilizing agent comprises a polyhydroxy fatty acid ester or a polyhydroxy fatty acid amide having the specific formulas as in claims 24 or 25 and an immobilizing agent such as paraffin wax are merely a matter of engineering design choice, and thus do not serve to patentably distinguish the claimed invention over the prior art. See In re Kuhle, 526 F.2d. 553, 188 USPQ 7 (CCPA 1975).

Applicant is also reminded that arguments toward the criticality of an element will generally be given little patentable weight. The basis for criticality should be disclosed in the specification or supplied by affidavit. See In re Cole, 140 USPQ 230 (CCPA 1964).

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 5,607,760; 5,609,587; 5,643,588 and 5,635,191 in view of Duncan (3,489,148).

Response to Arguments

6. Applicant's arguments filed 3/2/99 have been fully considered but they are not persuasive.

The examiner apologizes for any inconvience caused by the request for a copy of the abstract. After another review of the file, the original abstract was located. It has been moved to the proper location.

Applicant argues that Duncan does not teach the "application of a lotion composition on an article in a nonuniform manner" and that he teaches continuous application and that the droplets are formed due to the surface tension. The method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight. Additionally, Duncan teaches that it is desired to have a discontinuous film, such as one made from a multiplicity of discrete droplets to avoid a greasy look and feel, thus the use of dicrete droplets. (3:43-48)

A comparison of the recited process with the prior art process does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 Fed 742, 180 USPQ 324 (CCPA 1974). Whether a product is patentable depends on whether it is known in the art or is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 142 USPQ 161 (CCPA 1964), In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 190 USPQ 15, see footnote 3 (CCPA 1976).

Applicant next argues that the topsheet of Dreier cannot be combined with the topsheet of Duncan because the material cannot be both hydrophilic and hydrophobic and that applying Buchalter's formulation as droplets on the hydrophilic topsheet of Dreier's diaper would not achieve a discontinuous, localized coating. Thus, the proposed combination of references as suggested would change the principle of operation of the prior art invention. Applicant's arguments are unclear as the Examiner has not suggested placing Duncan's topsheet on Dreier's diaper or Duncan's topsheet with Buchalter's formulation on Dreier's diaper. The examiner stated that it would have been obvious to place Buchalter's formulation on Dreier's diaper in a discontinuous film such as a multiplicity of discrete droplets because Buchalter's formulation is a non-oily solid which is not oily to touch and does not require special packaging in oil resistant

paper (2:15-23) and Duncan teaches that a discontinuous film such as a multiplicity of discrete droplets aides in avoiding a greasy look and feel. (3:45-50)

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Dreier teaches the structure of the diaper, Buchalter teaches a solid composition as claimed for use on diapers, diaper liners and sanitary napkins and Duncan teaches a topsheet for a diaper which includes a lotion to alleviate diaper rash wherein the lotion is a discontinous film such a multiplicity of discrete droplets.

In response to Applicant's arguments that the Buchalter lotion will not work because it requires moisture, and bodily discharges often come in gushes, so that the skin will be exposed before the cream is formed. Nowhere in the Buchalter reference does it require gushes of fluid to form the cream. Buchalter teaches that "[i]n all such applications the contact of the wearer's skin will produce sufficient moisture and heat" to form the cream. Buchalter also teaches that the formulation is useful in gloves and shoe linings, there are not many gushes of fluid present in gloves and shoe linings. Thus, the moisture that is naturally present on the skin is sufficient to cause the cream to form and the formulation will inherently be transferred to the skin.

With respect to claims 24 and 25, whether the lotion is applied in stripes wherein the immobilizing agent comprises a polyhydroxy fatty acid ester or a polyhydroxy fatty acid amide having a specific formula as claimed or to use an immobilizing agent such as paraffin wax, the Examiner is not saying that it would be obvious to add these elements, but that these elements or features do not make the device patentably distinct.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 94/09757 cited by applicant discloses a cream and a lotion that can be applied to a diaper

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark O. Polutta whose telephone number is (703) 308-2114.

The examiner's supervisor, John Weiss, telephone number is (703) 308-2702. The fax phone number for official papers for this Group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Mark O. Polutta
May 11, 1999

MARK O. POLUTTA
PRIMARY EXAMINER
SECTOR 3700